UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRANCIS FENWICK et al., Plaintiffs, - against - RANBAXY PHARMACEUTICALS INC. et al., Defendants.	Case No. 3:12-cv-07354-PGS-DEA *DOCUMENT ELECTRONICALLY FILED*

MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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PRELIMINARY STATEMENT

Plaintiffs initially alleged that they were injured because they bought recalled Atorvastatin that was contaminated with glass particles, and they sought to represent a class of members who bought the same. That case fell apart in discovery when it became clear that not one of the five named Plaintiffs had any proof they actually bought contaminated Atorvastatin, and that most, if not all, other class members would have the same problem. As a result, Plaintiffs now seek to certify a truly remarkable class: *everyone* who bought Ranbaxy Atorvastatin from an inventory pool that *might* have contained some contaminated product—regardless of whether their bottles contained glass particles and regardless of whether those bottles even came from recalled lots—based on the novel theory that class members supposedly are harmed by the mere uncertainty of whether they might have bought Atorvastatin from an inventory pool that might have contained contaminated product.

As Plaintiffs' expert conceded, the proposed class includes members who indisputably did not buy Atorvastatin from the recalled lots—let alone bottles with glass particles. Because the recalled lots accounted for only 57% of Ranbaxy's total shipments of Atorvastatin during the recall period, the proposed class is based on a level of sales that is almost *double* the amount of recalled product. Nor does the proposed class account for 400,201 bottles that were returned as part of the recall—accounting for 80% of all bottles from recalled lots—which significantly reduced the likelihood that customers bought bottles that came from recalled lots. Even though at most 80,000 recalled bottles remained in the marketplace after the recall, Plaintiffs now seek to certify a class of 960,873 members—more than *10 times* as many members as there were non-recalled bottles.

Not surprisingly, Plaintiffs have not cited one case in which any court anywhere has certified a class where the vast majority of the class admittedly did not buy contaminated product. Nor do Plaintiffs cite, let alone distinguish, any of the many cases that squarely rejected similar

arguments. Different courts have declined to certify similar proposed class actions for different reasons, but the end result is the same—Plaintiffs' "uncertainty" theory is unsustainable. The same result should follow here because, as detailed below, Plaintiffs lack standing, have failed to prove ascertainability, have not met the four requirements of Rule 23(a), and have not shown either predominance or superiority under Rule 23(b)(3). This Court should deny Plaintiffs' class certification motion accordingly.

FACTUAL BACKGROUND[1]

I. Ranbaxy Recalls Certain Bottles of Atorvastatin in 2012 Due to a Possibility—Never Confirmed—that Some Bottles May Have Contained Tiny Glass Particles.

Ranbaxy manufactures Atorvastatin calcium tablets, a generic version of the brand drug Lipitor. (Pls.' 3d Am. Compl. ("Compl.") ¶ 21.) On November 9, 2012, Ranbaxy issued a recall for 41 lots of Atorvastatin consisting of 10 mg, 20 mg, and 40 mg tablets that were dispensed between September 25, 2012 and November 15, 2012. (*Id.* ¶ 28.) The recall affected 480,425 Atorvastatin bottles. (Ex. 1, Report of Dr. Bruce Strombom ("Strombom Rep.") ¶ 6; Ex. 2, RANBAXY_FEN0000131 (Excel summarizing quantities shipped in column E).)

The United States Food and Drug Administration ("FDA") did not mandate the recall; Ranbaxy voluntarily and proactively undertook it out of an excess of caution.[2] Specifically, Ranbaxy decided to recall certain lots of Atorvastatin "as a precautionary measure due to the fact that we cannot exclude the possibility" that those lots "may contain very small glass particles resembling a fine grain of sand (less than 1 mm in size)." (Ex. 4, PLTF00024.) At the time of

[1] Unless otherwise noted, all emphasis has been added, and all alterations, citations, and quotation marks have been omitted. "Mot." refers to Memorandum in Support of Plaintiffs' Motion for Class Certification (Dkt. 124-2).

[2] Throughout their motion, Plaintiffs repeatedly insist that the FDA "made" Ranbaxy conduct this recall. (*See, e.g.*, Mot. at 1.) This is not true. (*See, e.g.*, Ex. 3, RANBAXY_FEN0000103 (Ranbaxy advising FDA that although "it is still not definitively known" whether any glass particles made it into final product, "keeping the safety of our customers in mind, the company decided to *voluntarily* recall these batches out of abundance of caution.").)

recall, Ranbaxy could not "confirm if any of the lots of drug product we are voluntarily recalling do in fact contain any foreign substance." (Ex. 5, RANBAXY_FEN0000142-146, at 142.) And importantly, to this day, there has been no evidence that *any* of the 480,425 recalled bottles actually contained any glass particles. (*See* Ex. 6, Tr. of 30(b)(6) Dep. of Syed Qadry at 22:13-14.)

Ranbaxy announced the recall in a press release on November 28, 2012. Ranbaxy included the list of the 41 recalled lots in that notice as well as on its website, and it also instructed consumers on how to check whether their bottle came from one of those 41 lots.[3] Given the tiny size of the glass particles potentially at issue, Ranbaxy concluded that any possible contamination was "unlikely to cause a significant safety concern." (Ex. 4, PLTF00024-026.) Ranbaxy thus informed consumers that "the probability of an adverse event due to consumption of this product is remote" and that they "should NOT discontinue taking your atorvastatin without direct guidance from your doctor." (Ex. 7, RANBAXY_FEN0007129 (emphasis in original).)

Ranbaxy worked with FDA to coordinate the recall, and FDA oversaw each step of the process in a supervisory role.[4] FDA classified the recall as a Class II recall (Ex. 10, RANBAXY_FEN0001419), meaning that it was: (1) conducted at the retail level, not consumer level (Ex. 4, PLTF00024); and (2) FDA concluded that the risk of health problems from taking the recalled product was remote and outweighed by the risks from interruption in treatment that a consumer-level recall could produce. (Ex. 10, RANBAXY_FEN0001419; 21 C.F.R. § 7.41.)

On November 29 and 30, 2012, FDA issued its own statements on the recall. Consistent with what Ranbaxy had publicly announced, FDA told consumers that "[t]he possibility of adverse health problems related to the recalled atorvastatin is extremely low," and that "[p]atients who

[3] *See* Ex. 7, RANBAXY_FEN0007129; *see also* Ex. 8, Ranbaxy USA, Atorvastatin Recall: Helpful Information, http://www.ranbaxyusa.com/AnnounceDetail.aspx?id=16.

[4] *See* Ex. 9 Food and Drug Administration, FDA Statement on the Ranbaxy Atorvastatin Recall, http://www.fda.gov/Drugs/DrugSafety/ucm329951.htm (Nov. 29-30, 2012).

have the recalled medicine can continue taking it unless directed otherwise by their physician or health care provider."[5] FDA also told consumers that "[t]o date"—*i.e.*, three weeks after the recall was initiated—"FDA hasn't received any reports of injury." (*Id.*) Like Ranbaxy's recall notice, FDA's statement also included a list of the 41 lots, so that consumers could determine if they bought a bottle from one of those lots. (*Id.*)

The recall was highly effective. Ranbaxy instructed its retail customers (like wholesalers and pharmacies) to "[i]mmediately cease distribution" of the recalled product and to return it to Ranbaxy. (Ex. 5, RANBAXY_FEN0000142-146 at 143.) Ultimately, 400,201 of the 480,425 recalled bottles—over 80%—were returned. (Ex. 11, RANBAXY_FEN0000833-850, at RANBAXY_FEN0000850; Ex. 1, Strombom Rep. ¶ 7.) At most, only 20% of the recalled bottles—or about 80,000—ever reached consumers.

II. Plaintiffs Bring this Lawsuit, Alleging They Bought Atorvastatin with Glass Particles.

Plaintiffs filed this lawsuit on November 29, 2012, the day after the recall was announced. (Dkt. 1.) Plaintiffs' original theory of injury was clear: they alleged they bought "adulterated" Atorvastatin (*i.e.*, Atorvastatin that actually contained glass particles), they sought to represent a class of persons who likewise bought Atorvastatin contaminated with glass, and they sought damages based on the "value of the prescription pills purchased if they were not tainted and adulterated" (*i.e.*, the value of non-contaminated Atorvastatin).[6] Plaintiffs' three claims—breach of implied warranty of merchantability, breach of express warranty, and unjust enrichment—are all based on these alleged facts.[7] And importantly, it was these allegations—that Plaintiffs actually

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[5] Ex. 9, FDA Statement on the Ranbaxy Atorvastatin Recall.

[6] *See, e.g.*, Compl. ¶¶ 23-27 ("At no time was the plaintiff warned or notified that the product was adulterated or that *it contained a foreign substance*, to wit glass particles."); *id.* ¶¶ 55-56, 92 (asserting claims predicated on Plaintiffs' purchases of of "tainted" and "adulterated" pills); *id.*, Prayer for Relief.

[7] Because N.J. Stat. Ann. § 12A:2-314 codifies U.C.C. § 2-314, counts one and two assert the same claim. Likewise, because N.J. Stat. Ann. § 12A:2-313 codifies U.C.C. § 2-313, counts three and four assert the same claim.

bought Atorvastatin with glass particles—that persuaded this Court to allow the case to survive a motion to dismiss and proceed to discovery.[8]

III. Discovery Confirms that Plaintiffs Cannot Prove their Case on a Classwide Basis and that Plaintiffs' Claims Would Fail on the Merits in Any Event.

Plaintiffs' case fell apart in discovery when it became clear that even determining if a consumer bought a bottle of Atorvastatin that was affected by the recall—let alone whether the bottle was actually contaminated with glass particles—requires individualized inquiry. Discovery also revealed the total lack of evidence that *any* of the five named Plaintiffs bought Atorvastatin with glass, contrary to their allegations in the Complaint. Finally, depositions also established that Plaintiffs would face extraordinary hurdles in proving their claims even individually, let alone on a classwide basis—because named Plaintiffs admitted that if the bottles of Atorvastatin they bought did not contain glass particles, then there was nothing wrong with those bottles. Plaintiffs do not even acknowledge, let alone respond to, any of this evidence in their motion.

A. Only Three of the Five Named Plaintiffs Bought Bottles from Recalled Lots; There Is No Systematic Way to Identify Such Buyers.

There is no systematic way to determine if a consumer bought Atorvastatin from one of the 41 recalled lots—because companies do not track lot numbers when they buy drugs, nor when they sell them to individual consumers.[9] These challenges were illustrated by the difficulty in determining whether even the five named Plaintiffs bought Atorvastatin from the recalled lots. Two of them (Harding and Safran) were able to prove they did so through physical inspection of the bottles they bought in 2012—which they happened to keep, given their participation in this

[8] *See* Dkt. 59, Mar. 27, 2015 Tr. and Order Denying Motion to Dismiss, at 5:9-10 ("[COURT:] *there are glass particles in the Ranbaxy pills*, and plaintiffs object to ingesting same."); *see also id.* at 5:20-22 ("the bottom line is that the plaintiffs purchased [Ranbaxy pills] and *the pills were contaminated with glass particles*. The plaintiffs did not get what they paid for.") (quoting from Plaintiffs' brief, alteration in original).

[9] *See* Ex. 12, French Tr. at 127:14-20 (plaintiffs' expert agreeing that aside from examining individual bottles to identify their lot numbers, he is "not aware of any other documents, data or anything in this case that would allow [him] to determine on a class-wide basis whether consumers bought bottles from those 41 lots").

lawsuit—and comparing the lot number on their bottle to the list of recalled lots.[10] The likelihood that even a tiny fraction of the putative class actually kept their old bottles of Atorvastatin for over five years after the November 2012 recall and would now be able to identify their lot numbers is near zero. Indeed, both Harding and Safran agreed they would not have kept their bottles but for being named Plaintiffs in this lawsuit.[11] A third named Plaintiff (Young) no longer had her bottle of Atorvastatin, but she testified that her pharmacist told her that she bought a bottle from a recalled lot.[12] Adducing this kind of second-hand evidence on a classwide basis is impossible.

Discovery also confirmed that two of the five named Plaintiffs (Fenwick and Wardrett) did not buy bottles from the recalled lots, contrary to their allegations. Fenwick kept his bottle of Atorvastatin, also due to being a named Plaintiff; inspection of that bottle during his deposition revealed a lot number that did not match any of the recalled lots.[13] Wardrett did not keep her bottle, but her purchase records revealed that she bought her Atorvastatin before any of the recalled lots would have even reached her pharmacy.[14] The fact that two of Plaintiffs' five hand-picked representatives did not even buy *recalled* bottles does not inspire confidence that class membership and liability can be reliably and feasibly proved on a classwide basis—to say nothing of the much more complicated proof of who actually bought *contaminated* bottles.

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[10] Ex. 13, Harding Tr. at 100:12-25 (agreeing he was able to find this by "peel[ing] back the label from the bottle" and "look[ing] up the lot number on that bottle"); Ex. 14, Safran Tr. at 30:21-31:11 (agreeing he was "able to match the lot number" to the recall list because he "still had the bottle," "inspected" it, and identified its lot number).

[11] Ex. 13, Harding Tr. at 60:11-14 (agreeing he would not have "kept [his] bottle but for the fact that [he] filed this lawsuit"); Ex. 14, Safran Tr. at 87:5-8 (agreeing he would "have thrown away [his] bottle" had he not filed this suit).

[12] Ex. 15, Young Tr. at 98:6-19 (pharmacist advised her that her bottles "matched the batch numbers in the recall").

[13] Ex. 16, Fenwick Tr. at 89:18-21 (agreeing he did not keep other Atorvastatin bottles he bought in 2012 because "I don't have a collection of ancient pill bottles"); *id.* at 171:6-14 (agreeing his bottle "is not part of the affected lots").

[14] Ex. 17, Wardrett Tr. at 187:2-9 (agreeing she bought her bottle "before the recall[ed] product was distributed to CVS").

B. None of the Five Named Plaintiffs Bought Contaminated Atorvastatin.

Plaintiffs filed this case premised on the allegation that they bought Atorvastatin contaminated with glass. But after discovery, not *one* of the five named Plaintiffs is able to prove this allegation. Fenwick and Wardrett did not even buy Atorvastatin from recalled lots, so their bottles obviously were not contaminated.[15] Safran still had his bottle, which did come from a recalled lot, but he did not "know one way or the other whether the pills contain any glass particles"; he agreed that to find out, it would be necessary to "test the pills." (Ex. 14, Safran Tr. at 126:9-17.) Harding, who also still had his bottle, "did not see any glass particles in the bottle or in any of the pills." (Ex. 13, Harding Tr. at 97:21-98:6.) Finally, Young also "didn't see any glass particles" in the bottles of Atorvastatin that she bought. (Ex. 15, Young Tr. at 108:24-109:4.)

This lack of proof is not surprising, because as detailed at pages 2-3 above, there is no evidence that *any* of the recalled bottles were actually contaminated with glass. With no proof that any bottles were defective, Plaintiffs now argue that Ranbaxy had identified minute glass particles in certain batches of the active pharmaceutical ingredient ("API") used to produce Atorvastatin, and that those batches were then converted into Atorvastatin pills that went into the 41 recalled lots. (Mot. at 7.) This is not true: there simply is no evidence that any glass particles were observed in the API that was used to manufacture the 41 recalled lots.[16] Ranbaxy recalled the 41 lots out of an excess of caution and because it could not rule out the possibility that some of the manufactured product may have contained glass particles.[17] As Ranbaxy's Rule 30(b)(6) witness testified, the

[15] Fenwick "just assumed" that his bottle "contained glass particles" because he thought it came from a recalled lot. (Ex. 16, Fenwick Tr. at 125:15-18; *see also id.* at 124:1-5 (agreeing that his "only basis" for believing his bottle was contaminated was his belief that that bottle "was part of the lot that was recalled").) Wardrett agreed she had "no idea whether the bottle [she] bought in 2012 actually had glass particles in it." (Ex. 17, Wardrett Tr. at 167:10-15.)

[16] *See* Pls.' Ex. 3, at RANBAXY_FEN0000103 (API used for the 41 lots was made "subsequent" to API with glass).

[17] *See* Ex. 5, RANBAXY_FEN0000142-146, at 142 (Ranbaxy could not "confirm if any of the lots of drug product we are voluntarily recalling do in fact contain any foreign substance").

company never confirmed that any of the recalled bottles actually contained glass particles.[18] (Ex. 6, Qadry 30(b)(6) Tr. at 22:13-14.) And the fact that FDA did not receive any reports of injuries associated with the recalled bottles (*see* Ex. 9 at 1) further suggests that no bottles were contaminated.

C. Class Representatives Refute Plaintiffs' New "Uncertainty" Theory.

Plaintiffs now argue that their inability to prove that any bottles were actually contaminated is of no moment, because class members supposedly are harmed by mere uncertainty of whether they *might* have bought Atorvastatin from an inventory pool that *might* have contained contaminated product. Not only does such speculation fails to establish an Article III injury (Section I below), but this new theory is foreclosed by named Plaintiffs' own sworn testimony.

Named Plaintiffs initially assumed that the bottles of Atorvastatin they bought must have contained glass particles simply because those bottles were recalled.[19] The evidence has now shown that to be untrue. After being faced with evidence in depositions that Ranbaxy was unable to confirm if any contamination actually occurred, named Plaintiffs all admitted that just because a particular bottle came from a recalled lot does not mean it actually contained glass particles.[20] Named Plaintiffs also all agreed they have no reason to believe that the bottles they bought were not pharmaceutically effective or were not pharmaceutically equal to brand-name Lipitor.[21] And,

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[18] FDA urged Ranbaxy to destroy the Atorvastatin that was returned during the recall period just one month after the recall, to minimize the likelihood of any inadvertent misuse or shipment. (Ex. 10, RANBAXY_FEN0001419.) Ranbaxy did so with FDA's approval and supervision. (Ex. 18, RANBAXY_FEN00006130.)

[19] Ex. 13, Harding Tr. at 97:6-9 (agreeing it was his "assumption that [his] bottle of atorvastatin contains glass particles just because it was subject to the recall"); Ex. 14, Safran Tr. at 230:4-8 (agreeing that his "only basis for challenging the integrity of [his] bottle is that it was part of a recall[,] not that it actually contained glass particles").

[20] Ex. 14, Safran Tr. at 102:12-18 (agreeing that "just because a particular bottle of atorvastatin was recalled in 2012, that does not mean that that bottle actually contained glass particles"); Ex. 13, Harding Tr. at 78:2-7 (same); Ex. 16, Fenwick Tr. at 125:1-5 (same); Ex. 17, Wardrett Tr. at 141:23-142:11 (agreeing she had no reason to believe that every recalled bottle contained glass particles); Ex. 15, Young Tr. at 48:20-49:9 (same).

[21] Ex. 14, Safran Tr. at 233:1-6 (agreeing that if his bottle of Atorvastatin did not contain glass particles, then that "bottle is of the same quality, safety, and purity as brand name Lipitor"); Ex. 15, Young Tr. at 185:16-24 (agreeing she has "no reason to believe" that her Atorvastatin was "any less medically effective than brand name Lipitor"); Ex.

named Plaintiffs also all admitted that if the bottles they bought did not actually contain glass particles, then those bottles were *not* defective.[22] Named Plaintiffs also admitted that Ranbaxy did *not* breach any warranties by selling bottles that were not contaminated with glass,[23] and that Ranbaxy was *not* unjustly enriched by selling those bottles.[24] Indeed, certain named Plaintiffs even admitted that if their Atorvastatin bottle did not contain glass, they would not be appropriate class representatives and they should not be part of this lawsuit.[25]

Speculation by Plaintiffs' counsel about harm from supposed "uncertainty" aside, sworn testimony from class representatives makes clear that if they did not actually buy a bottle containing glass particles—and none of them have proof they did—then they have not suffered any injury. The same will be true for other putative class members. And, of course, the question of whether any of the 960,000-plus members in Plaintiffs' proposed class in fact bought a bottle contaminated with glass particles will need to be resolved on a member-by-member basis, through physical inspection of their bottles—which the vast majority of the class no longer has. This is the antithesis of an issue that can be resolved on a classwide basis.

16, Fenwick Tr. at 178:10-14 (agreeing he is not claiming that his bottle of Atorvastatin "was any less effective than brand name Lipitor in treating [his] medical condition"); Ex. 13, Harding Tr. at 135:1-6 (agreeing he is not claiming that his Atorvastatin "was any less effective in treating [his] cholesterol than brand name Lipitor"); Ex. 17, Wardrett Tr. at 210:10-14 (agreeing that her bottle of Atorvastatin "was just as medically effective as brand name Lipitor.")

[22] *See* Ex. 16, Fenwick Tr. at 190:21-24 (agreeing that "if the bottle doesn't contain glass particles, then there is nothing wrong with it"); Ex. 13, Harding Tr. at 143:6-10 (agreeing that "if a bottle of atorvastatin doesn't actually contain any glass particles, there is nothing wrong with the quality and integrity of that bottle"); Ex. 15, Young Tr. at 193:15-22 (agreeing that if her bottle did not contain glass, she has no "reason to believe there was something else wrong with the pills in the bottle that [she] bought"); Ex. 17, Wardrett Tr. at 165:22-166:5 (agreeing that if her bottle did not contain glass, she had no other reason to think there was something wrong with it); Ex. 14, Safran Tr. 134:3-8 (same).

[23] *See* Ex. 13, Harding Tr. at 144:15-20 (if the bottle "did not actually contain glass particles, then it's inaccurate to say that defendant breached their warranties with respect to that bottle"); Ex. 16, Fenwick Tr. at 185:14-19 (same).

[24] *See* Ex. 17, Wardrett Tr. at 231:11-17 (agreeing that if her bottle did not contain glass particles, she does not "think Ranbaxy would have been unjustly enriched" by selling her that bottle); Ex. 16, Fenwick Tr. at 190:25-191:3 (agreeing that "Ranbaxy was not unjustly enriched by selling those bottles that had no glass particles").

[25] Ex. 16, Fenwick Tr. at 128:23-129:2 (agreeing that if his bottle of Atorvastatin "did not contain glass particles, [he] should not [be] part of this class action"); *id.* at 133:16-134:2 (agreeing that if his bottle did not contain glass particles, he "would not be a good representative" for other class members); Ex. 13, Harding Tr. at 108:17-22 (agreeing that "if this particular bottle of atorvastatin that [he] bought did not actually contain glass particles, [he] should not be part of this case"); *id.* at 109:13-17 (if his bottle did not contain glass, he "would not be an appropriate class representative").

IV. Plaintiffs Now Try to Certify a Class that Mostly Consists of Members Who Did Not Even Buy Recalled Atorvastatin, Let Alone Atorvastatin that Was Contaminated.

Recognizing that they cannot prevail on their original theory—that class members were harmed because they bought Atorvastatin contaminated with glass—Plaintiffs now move to certify an entirely different class: *all purchasers* of certain National Drug Codes ("NDC") of Atorvastatin sold during the recall period, regardless of whether their bottles contained glass particles, and regardless of whether those bottles even came from recalled lots. (*See* Mot. at 4.)

This extraordinary "inventory pool" theory of liability has never been recognized by any decision of which Ranbaxy is aware. And this theory is also irreconcilable with the record in this case. It flies in the face of the total lack of evidence that any recalled bottles were actually contaminated. It cannot be squared with FDA's own determination that "the possibility of adverse health problems related to the recalled atorvastatin is extremely low," and its instruction that "patients who have the recalled medicine can continue taking it" unless told otherwise by their doctor. (Ex. 9.) And theory was also rejected by named Plaintiffs themselves, who testified that if their bottle of Atorvastatin did not contain glass particles, then there was *nothing wrong* with that bottle and that they should not even be a part of this lawsuit. (*Supra* at 8-9.)

Moreover, as Plaintiffs' expert conceded, this "inventory pool" class would include members who indisputably did not even buy Atorvastatin from the recalled lots—let alone bottles with glass particles.[26] This is not a hypothetical issue: because the 41 recalled lots accounted for only 57% of Ranbaxy's total shipments of Atorvastatin during the recall period, Plaintiffs' proposed class is "based on a level of sales that is almost *double* the amount of recalled product." (Ex. 1, Strombom Rep. ¶ 52.) Nor does Plaintiffs' proposed class account for 400,201 bottles that

[26] Ex. 12, French Tr. at 148:19-22 (agreeing that "the proposed class and [his] damages model . . . does not try to limit the class to the 41 recalled lots"); *id.* at 156:7-12 (agreeing that "this inventory pool approach would also capture sales of bottles that came in from non-recalled lots that the company received during the recall[] period").

were returned—accounting for 80% of all bottles from recalled lots—which significantly reduced the likelihood that customers bought bottles from those lots. (*Id.*) And even though at most 80,000 recalled bottles remained in the marketplace after the recall, Plaintiffs now seek to certify a class of 960,873 members—more than *10 times* as many members as there were non-recalled bottles.

ARGUMENT

Plaintiffs have not carried their heavy burden to certify a Rule 23(b)(3) class for multiple reasons. *First*, Plaintiffs' new liability theory—that they were harmed by mere "uncertainty"—is far too speculative to show injury-in-fact, and this class action should be dismissed for lack of Article III standing. (Sec. I.) Plaintiffs also cannot pursue their original liability theory—that they actually did buy contaminated Atorvastatin—because not one of the five named Plaintiffs could offer any proof that he or she in fact did so. (Sec. I.)

Second, Plaintiffs have failed to prove that their proposed class is ascertainable. (Sec. II.B.) Plaintiffs' sole proposed way of ascertaining the class is through the report of their damages expert, Dr. Gary French. But Dr. French did not even purport to develop a method to reliably identify all members of the class; he concedes his model is not capable of doing so based on available data; and Plaintiffs in any event lack consumer-level data that would allow them to identify much of their proposed class.

Third, Plaintiffs have also failed to prove predominance under Rule 23(b)(3). (Sec. II.C.) Court after court has found no predominance in recall cases like this one—where there is no single defect that affects every product at issue, and where determining if class members in fact bought defective product, not just a recalled product, requires individual inquiry. Nor have Plaintiffs carried their burden to prove superiority under Rule 23(b)(3), given the many individualized questions to be decided for each member in this nationwide class—an inquiry exponentially complicated by the fact that the laws of each class member's home state would apply. (Sec. II.D.)

Finally, in addition to all these insuperable obstacles under Rule 23(b)(3), Plaintiffs also have not proven that they met the four requirements of Rule 23(a): commonality, typicality, adequacy, and numerosity. (Sec. II.E.) Plaintiffs have not shown commonality because key issues here are not capable of classwide resolution. (Sec. II.E.1.) Typicality and adequacy are likewise absent because named Plaintiffs have failed to show they bought contaminated Atorvastatin (unlike other class members who may have), and they also would be subject to unique defenses (such as, for instance, that their Atorvastatin did not manifest a defect, and that they are unaware of any warranties from Ranbaxy). (Sec. II.E.2.) And Plaintiffs also have not proven numerosity because their proposed "inventory pool" class is overbroad, yet they offer no proof that the number of people who actually bought contaminated Atorvastatin is sufficiently numerous. (Sec. II.E.3.)

I. Plaintiffs' Supposed "Uncertainty" Is Not a Cognizable Article III Injury.

Plaintiffs' current "uncertainty" theory—borne of necessity when Plaintiffs were left with no evidence of actual contamination following discovery—is far too speculative to show that class members have suffered an Article III injury-in-fact. With no standing, this class action fails.

To have Article III standing, a plaintiff must show "an injury in fact"—that is, "a concrete and particularized invasion of a legally protected interest." *Common Cause of Pa. v. Pennsylvania*, 558 F.3d 249, 258 (3d Cir. 2009). An injury "based on speculation" or "contingent on future events" will not suffice. *Berg v. Obama*, 586 F.3d 234, 239 (3d Cir. 2009).

The "injury in fact" requirement holds true in the class context too. Plaintiffs "must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Warth v. Seldin*, 422 U.S. 490, 502 (1975). A named plaintiff "who lacks the personalized, redressable injury required for standing to assert claims on his own behalf would also lack standing to assert similar claims on behalf of a class." *Holmes v. Pension Plan of Bethlehem Steel Corp.*,

213 F.3d 124, 135 (3d Cir. 2000) (same). The need to prove standing must be satisfied before a class can be certified. *See, e.g.*, *Hassine v. Jeffes*, 846 F.2d 169, 176 (3d Cir. 1988).

First, it is now clear that named Plaintiffs cannot represent the original class proposed in the Complaint—a class of persons allegedly harmed by buying Atorvastatin with glass. With no evidence that any of named Plaintiffs actually bought contaminated Atorvastatin, they obviously cannot represent a class of members who allegedly did so. Indeed, named Plaintiffs themselves admit as much. (*See supra* at 8-9.) And courts routinely dismiss claims asserted by named plaintiffs who themselves were not injured by the defect that allegedly harmed the rest of the class. *See, e.g.*, *In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 273 (E.D. Pa. July 13, 2012) (dismissing named plaintiffs' claims for lack of standing because an injury must affect the plaintiff "in a personal and individual way," and "[t]he fact that other persons suffered adverse effects . . . does not suffice to establish injury in fact as to this group.").[27]

Second, Plaintiffs' fallback theory—that regardless of whether they bought contaminated Atorvastatin, they were harmed by mere uncertainty of buying Atorvastatin from an inventory pool that *potentially* contained contaminated product—does not give them standing either. For one, this theory is foreclosed by named Plaintiffs' admissions that if their bottles of Atorvastatin did not contain glass particles, then there was nothing wrong with those bottles. (*See supra* at 8-9.) Additionally, any alleged uncertainty here is illusory, since the only Atorvastatin that may have even potentially contained glass would have come from the 41 recalled lots, and customers could

[27] *See also River v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 320 (5th Cir. 2002) (no standing where "plaintiffs claim that Wyeth violated the implied warranty of merchantability by selling a defective drug, but then aver that the drug was not defective as to them," and "claim Wyeth violated the DTPA by failing to issue warnings sufficient to advise injured users, but then concede they were not among the injured," because "such wrongs cannot constitute an injury in fact."); *Ironworkers Local Union 68 v. AstraZeneca Pharms.*, 634 F.3d 1352, 1363 (11th Cir. 2011) (to demonstrate economic injury, a plaintiff must allege that "the drug was unsafe or ineffective for its prescribed use"); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 380 (D.N.J. 2004) (no injury where plaintiffs did not allege drug was defective as to them).

have determined if they bought such a bottle by examining it and comparing the lot number to the list of recalled lots. Any supposed "uncertainty" here is the result of customers failing to check lot numbers on their bottles or deciding not to do so; either way, it is not attributable to Ranbaxy.

Finally, this liability theory—which piles speculation upon speculation—in any event is not enough, because courts routinely find this kind of hypothetical uncertainty to be too "speculative" and "subjective" to establish an injury-in-fact. *See, e.g.*, *Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (3d Cir. 2010) (finding lack of standing because plaintiff had suffered no adverse health effects from using the product, and offered "only a subjective allegation that the trace amounts of lead in the lipsticks are unacceptable to her").[28]

II. Plaintiffs Have Failed to Meet Their Rule 23 Burden to Certify a Class.

Plaintiffs also have not carried their burden under Rule 23. Section II.A below sets forth the Third Circuit's framework for Rule 23 analysis. Section II.B addresses why Plaintiffs failed to prove that their proposed class is ascertainable. Sections II.C and II.D show that Plaintiffs failed to satisfy either predominance or superiority, precluding certification of their proposed Rule 23(b)(3) class. And Section II.E shows that Plaintiffs also failed to meet the four requirements of Rule 23(a) (commonality, typicality, adequacy, and numerosity).

A. Plaintiffs Face a Heavy Burden in Certifying a Class and Must Prove Each Rule 23 Requirement by Preponderance of the Evidence.

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Comcast Corp. v. Behrend*, 569 U.S. 27, 33 (2013). "To come within the exception, a party seeking to maintain a class action must affirmatively

[28] *See also Estrada v. Johnson & Johnson*, 2017 WL 2999026, at * 9 (D.N.J. July 14, 2017) (finding lack of standing because "absent an allegation of adverse health consequences from using Baby Powder, or that Baby Powder failed to perform satisfactorily for its intended use, Plaintiff cannot claim that she was denied the benefit of her bargain"); *James v. Johnson & Johnson Consumer Companies, Inc.*, 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011) (finding that plaintiffs' "fear of future injury is legally insufficient to confer standing," and that "plaintiffs received the benefit of their bargain so long as there were no adverse health consequences, and the product worked as intended").

demonstrate his compliance with Rule 23." *Id.* As the Third Circuit repeatedly explained—and as this Court just recently acknowledged—that means that "*actual*, not presumed, conformance with Rule 23 requirements is essential," and the plaintiff "bears the burden of establishing each element of Rule 23 by a preponderance of the evidence." *Hargrove v. Sleepy's, LLC*, 2018 WL 1092457, at *4 (D.N.J. Feb. 28, 2018) (Sheridan, J.) (quoting *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 591 (3d Cir. 2012)).

"Plaintiff's burden" to certify a class "is a heavy one." *Gordon v. Maxim Healthcare Servs., Inc.*, 2017 WL 3116153, at *5 (E.D. Pa. July 21, 2017). "To determine whether there is actual conformance with Rule 23, a district court must conduct a 'rigorous analysis' of the evidence"; "when doing so, the court cannot be bashful" and it cannot "shy away from making factual findings." *Marcus*, 687 F.3d at 591. Instead, the district court "*must* resolve all factual or legal disputes relevant to class certification, even if they overlap with the merits—including disputes touching on elements of the cause of action." *Id.*; *Reyes v. Netdeposit, LLC*, 802 F.3d 469, 484 (3d Cir. 2015) (emphasizing that Rule 23 requires a "rigorous analysis" and a "searching inquiry" by the district court, and that class certification "calls for findings by the court, not merely a threshold showing by a party, that each requirement supporting Rule 23 findings is met").

This rigorous analysis is further heightened when, as here, plaintiffs seek to certify a class under Rule 23(b)(3)—"an adventuresome innovation . . . designed for situations in which class-action treatment is not as clearly called for." *Behrend*, 569 U.S. at 34. Certification under Rule 23(b)(3) requires plaintiffs to further prove both that: (1) "questions of law or fact common to class members predominate over any questions affecting only individual members" (*i.e.*, predominance); and (2) "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy" (*i.e.*, superiority). Plaintiffs here come nowhere close.

B. Plaintiffs Have Failed to Show that Their Proposed Class Is Ascertainable.

Ascertainability is an "essential prerequisite of a [Rule 23(b)(3)] class action." *Carrera v. Bayer Corp.*, 727 F.3d 300, 306-7 (3d Cir. 2013). "The rigorous analysis requirement applies . . . to the ascertainability inquiry." *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015).

To establish ascertainability, Plaintiffs must show, by preponderance of evidence, that the class is "currently and readily ascertainable based on objective criteria." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 592-93 (3d Cir. 2012). This "inquiry is two-fold, requiring a plaintiff to show that: (1) the class is defined with reference to objective criteria; and (2) there is a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Byrd*, 784 F.3d at 163. Administrative feasibility "means that identifying class members is a manageable process that does not require much, if any, individual factual inquiry"; thus, ascertainability does not exist "if individualized fact-finding or mini-trials will be required to prove class membership." *Carrera*, 727 F.3d at 307-308.

Plaintiffs' threadbare showing cannot withstand even superficial scrutiny—let alone the "rigorous analysis" this Court must apply. *Byrd*, 784 F.3d at 163. First, Plaintiffs offer virtually no evidence of ascertainability. Plaintiffs' arguments on this issue are filled with unsupported assertions by counsel and assurances that members can be identified. (Mot. at 14-16.) But counsel argument is not evidence. Instead, Plaintiffs need to offer enough proof to allow this Court to find—by preponderance—that this large class indeed is ascertainable. They have not done so.[29]

Second, the sole piece of evidence on which Plaintiffs do rely for ascertainability—a damages expert report by Dr. Gary French—in fact does not provide a "mechanism for identifying

[29] *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149-50 (E.D. Pa. 2015) (finding ascertainability not met where plaintiffs put forth only "scant evidence" and assurances, and noting that "the Third Circuit has warned district courts against merely relying on a party's assurance" that it will satisfy Rule 23).

the class members." (Mot. at 15.) This is so for multiple reasons: (1) Dr. French opined on damages and did not purport to come up with a way to reliably identify all members of the class; (2) Dr. French's damages model is based on a sample of just four companies out of the 35 that sold the recalled Atorvastatin, and Plaintiffs failed to obtain consumer-level data for most of those 35 companies, making identification of consumers impossible;[30] (3) Dr. French admits that even the limited consumer-level data on which he relied does *not* identify individual purchasers; and (4) even ignoring all these issues and assuming that Dr. French's model could be extended to the entire nationwide class (and it cannot), the model does not fit the class definition because it does not exclude members who bought Atorvastatin from non-recalled lots, and Plaintiffs in fact admit it is *impossible* to exclude them. These points are addressed in turn below.

Dr. French did not opine on ascertainability. Dr. French did not even purport to come up with a way to identify individual class members in a reliable and administratively feasible way. Instead, he was "asked by plaintiff's counsel to determine if there is a feasible methodology for determining *class damages* in this matter." (Ex. 19, French Rep. ¶ 7.) Dr. French thus came up with a sample damages model based on transaction data from just four companies—out of 35 total—that sold the recalled Atorvastatin. (*Id.* ¶ 7 & n.4.)[31] One of these four companies (Kroger) did not even produce consumer-level data, even though Dr. French acknowledged that Kroger accounts for a "fairly large" portion of the sold Atorvastatin at issue. (Ex. 1, Strombom Rep. ¶ 43;

[30] It is unclear from Plaintiffs' motion whether they seek to certify a class of members who bought from all 35 companies at issue or only a subset of them. (*See* Mot. at 4 (proposing a class of purchases from "certain pharmacies and mail order facilities").) Either way, the proposed class is not ascertainable for reasons detailed below.

[31] The morning of Dr. French's deposition, Plaintiffs' counsel produced tables with consumer-level damages for three more companies: Osborn, Discount Drug Mart, and Winn-Dixie. (Ex. 12, French Dep. Tr. at 6:5-7:4.) Dr. French has not opined that class members who bought from these companies can be readily identified. That same morning, Plaintiffs also produced a damages table for CVS. But as Dr. French testified, this was only a "ballpark estimate," which did not "us[e] CVS data that you would want to need" for "a real estimate of the damages." (*Id.* at 45:11-17.) The CVS data does not identify consumer-level sales (*see* Ex. 19, French Rep. ¶ 33; Ex. 20, Strombom Dep., Ex. 18, Letter from L. Sullivan to B. Gainey, at 3-4), and so it also cannot be used to identify individual class members.

Ex. 12, French Tr. at 75:20-76:4).). Even if Dr. French's damages model could be used to reliably identify members—which he himself does not contend—that model cannot be applied to identify members who bought recalled Atorvastatin from most of the stores that sold it.

Lack of consumer-level data. The reason that Dr. French's damages model is limited to a handful of companies is simple: Plaintiffs do not have consumer-level data for Atorvastatin sales for most of the 35 companies at issue. Ranbaxy does not sell Atorvastatin to individual consumers directly; it sells its products to wholesalers and retailers. (*See* Ex. 21, Ranbaxy Supp. Response to Pls.' Interrogatory No. 15.) There is no Ranbaxy database that would allow Plaintiffs to identify individual consumers who bought the recalled Atorvastatin. Instead, as Plaintiffs recognize, they had to obtain this data through "third-party discovery from the 35 companies that received the recalled pills." (Dkt. 110, Pls.' June 12, 2017 Letter Br. to Court, at 3.) This task is further complicated by the fact—which, again, Plaintiffs recognize—that "some of the [35] companies are wholesalers who sold to retailers"; Plaintiffs cannot obtain customer-level information from those wholesalers directly, and they instead "need to track those bottles downstream to the retailers"—which means subpoenaing individual pharmacies. (*See* Dkt. 110 at 3.)[32] Importantly, Plaintiffs *did* try obtain this data from all 35 companies via subpoenas.[33] And indeed, Plaintiffs requested and received repeated extensions for third-party discovery precisely so that they could obtain this data. (*See* Dkts. 71, 90, 101, 110, 112, 115.)

Despite having many months to conduct third-party discovery, and despite issuing subpoenas to all companies at issue, Plaintiffs have obtained consumer-level data for only *seven* of the 35 companies. (*See* Ex. 1, Strombom Rep. ¶ 62 & Fig. 9.) 19 of the 35 companies

[32] As Plaintiffs' expert Dr. French admitted, "to date, no wholesaler in this case has produced any data that would show atorvastatin sale[s] at the individual retail pharmacy level." (Ex.12, French Tr. at 113:16-22.)

[33] Ex. 22, Tr. of Aug. 8, 2017 Court Conf. at 12:3-15 (Plaintiffs' counsel stating that he served deposition and document subpoenas on all of the 35 companies that are still in business and that could be located).

apparently produced no data at all as of the date of Dr. French's report.[34] And certain companies—most notably including CVS, which sold a significant amount of the recalled Atorvastatin—did not produce any consumer-level data.[35] So despite knowing that they need this consumer-level data and seeking it through subpoenas, to this day, Plaintiffs do not have it for most of their proposed class. As courts recognize, such "incomplete transactional data was rejected by the Third Circuit as a reliable method for ascertaining class membership." *In re Domestic Drywall Antitrust Litig.*, 2017 WL 3700999, at *9 (E.D. Pa. Aug. 24, 2017).[36]

Plaintiffs argue that ascertainability "does not mean that a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that 'class members *can* be identified.'" (Mot. at 15 (emphasis in original).) But Plaintiffs have *not* shown that members can be identified. To the contrary, despite trying, Plaintiffs have failed to obtain much of the data they need. Such unsuccessful discovery efforts weigh heavily against a finding of ascertainability. *See In re Wellbutrin*, 308 F.R.D. at 150 (finding lack of ascertainability, and remarking that the fact that plaintiffs had "served subpoenas" on third parties for data to identify class members "but did not obtain any records" from them "heightens the Court's concern that such . . . records may not be obtainable for use in the ascertainability inquiry"). Nothing in the present record can support a finding by this Court, by a preponderance of the evidence, that there is a way to readily identify even a fraction of the class—let alone the entire class.

[34] *See id.* (addressing Dr. French's analysis of four entities, and discussing data produced by Dr. French "from an additional 12 third party entities"). After fact and expert discovery closed, Plaintiffs also belatedly produced data and a declaration from Express Scripts, Inc. and Medco. Defendants moved to exclude this untimely produced data, and that motion is pending with Magistrate Judge Arpert. (Dkts. 125, 129.)

[35] Ex. 23, July 24, 2017 CVS Health's Responses and Objections to Plaintiffs' Subpoena, at 6 (objecting to Plaintiffs' request for documents related to the "identity of the consumers" to whom the Atorvastatin at issue was sold).

[36] *See also id.* (finding no ascertainability in proposed class of drywall purchasers where the "best, most objective evidence" of class membership consisted of "records from the big box stores, but Plaintiffs admit that the transactional data available from those stores is limited where available, and is not available from all retailers").

Data produced to date does not identify class members. Dr. French also admitted that even for those few companies that did produce consumer-level data, that data cannot be used to identify members. He testified that the databases he reviewed "have a consumer identifier code in them, and now, they generally redact the consumer's name as confidential." (Ex. 12, French Dep. Tr. at 84:12-14.) While he speculated that identifying individuals may be possible "with further discovery," he conceded that "you can't do it right now looking at the data."[37] But again, the time for Plaintiffs to prove that members can be ascertained and identified is now—not "after the class is certified," as Plaintiffs argue. *See* Mot. at 16; *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 358 (3d Cir. 2013) ("the trial court cannot take a wait-and-see approach to . . . any . . . requirement of Rule 23").[38] Plaintiffs have failed to make this showing.

Dr. French's damages model cannot identify members under Plaintiffs' proposed class definition. Even setting aside all the above deficiencies, Dr. French's model also cannot be used to ascertain the class for a very basic reason: the class definition *excludes* members who bought Atorvastatin from non-recalled lots, while Dr. French's model *includes* them. Specifically, Plaintiffs' proposed class "excludes any consumers who are known with certainty to have received pills that were not from the [41] recalled lots" (Mot. at 4-5)—not surprisingly, since such members cannot claim any conceivable harm. But Dr. French admitted that his model "does not try to limit the class to the 41 recalled lots," and he agreed that his model "would also capture sales of bottles that came in from non-recalled lots." (Ex. 12, French Tr. at 148:19-22, 156:7-12.)[39] Dr. French

[37] *Id.* at 84:18-85:6; *see also id.* at 85:9-115 (agreeing that "based on data that we have to date . . . for all these companies at issue, it's not possible to specifically identify consumers by name").

[38] *See also Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *10 (E.D. Pa. June 10, 2015) (in the Third Circuit, "[p]laintiffs must, *at the time of class certification*, present a methodology to identify class members, and prove by a preponderance of the evidence that such methodology will be effective and will not require extensive individualized inquiry and mini-trials") (emphasis in original).

[39] *See also id.* at 138:17-139:2 (agreeing his model "calculates damages on pills subject to the recall as well as pills *not* subject to the recall"); *id.* at 139:6-12 (agreeing his "methodology doesn't distinguish between pills that came from the 41 lots that were subject to the recall versus pills that were not from those 41 lots").

also admitted there is no data "that would allow [him] to determine on a class-wide basis whether consumers bought bottles from those 41 [recalled] lots." (*Id.* at 127:14-128:3.) Thus, there is a basic and fundamental mismatch between the class definition and the damages model on which Plaintiffs propose to rely to identify members.

This is not a problem that could be fixed with more discovery, even if discovery had not already closed, because such data—*i.e.*, consumer-level sales data that tracks lot numbers—does not exist. Dr. French admitted as much, stating that most "retail pharmacy companies did not track the lot numbers" when receiving Atorvastatin from distribution centers, and that they also "did not track the lot numbers for pills dispensed to consumers." (Ex. 19, French Rep. ¶ 16; *see also id.* ¶ 17 (same for mail-order pharmacies).) Instead, these companies track sales to customers by National Drug Codes, not lot numbers. (*See id.*) But as Dr. French also admitted, NDCs are "not lot specific," and using "NDCs rather than lots . . . [is] going to capture not just the 41 lots that were recalled," but also products that "came from different lots." (Ex. 12, French Tr. at 137:7-10, 138:7-12.) Given these data limitations, Dr. French conceded that "at this point in time, there's very likely no feasible way to accurately identify what persons actually bought bottles of Atorvastatin that was recalled in 2012." (*Id.* at 179:9-13.)

C. Plaintiffs Have Failed to Prove Predominance Under Rule 23(b)(3).

The predominance requirement of Rule 23(b)(3) is "far more demanding" than that of commonality under Rule 23(a)(2), *Amchem Products Inc. v. Windsor*, 521 U.S. 623-24 (1997); thus, Ranbaxy addresses predominance before commonality.

Predominance requires Plaintiffs to prove that common issues predominate over individual ones. This "inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation," which "calls upon courts to give careful scrutiny to the relation between common and individual questions in a case." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S.

Ct. 1036, 1045 (2016). "An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Id.*

The overwhelming number of individual inquiries here predominate over any common ones for two independent reasons: (1) Plaintiffs' claims turn on individual factual questions that are incapable of classwide proof; and (2) the laws of 50 states would apply to Plaintiffs' proposed nationwide class, which means that common legal issues do not predominate.

1. Common Factual Issues Do Not Predominate.

Plaintiffs cannot identify even one case that has certified a class action in similar circumstances—*i.e.*, where there is no evidence that any of the recalled product was actually contaminated, and where only a small subset of the class could have even bought the recalled product (let alone product that was actually contaminated). Nor have Plaintiffs identified even one case that holds that merely buying a recalled product is enough to prove that that product was actually defective. That is not surprising because courts, in fact, hold the opposite.

For example, in a very similar case involving the drug Lipitor, where a broad recall was issued because a small number of sold Lipitor bottles were found to be counterfeit, the court squarely rejected the plaintiffs' attempt to prove defect simply by virtue of the recall taking place. *Arons v. Rite Aid Corp.*, 2005 WL 975462, at *3-4, 10 (N.J. Sup. Mar. 23, 2005) ("plaintiffs may not rely upon the happening of the voluntary recall as a basis to argue that the goods acquired from the retail pharmacies, in fact, were not authentic," particularly where "the evidence supports the reasonable inference that the vast majority of the tablets sold and resold by the defendants were probably authentic"). And in another very similar case—where baby formula Similac was recalled due to contamination with beetles, but evidence indicated that only 0.16% of the recalled product

was actually contaminated—the court likewise rejected the notion that every recalled bottle should be deemed defective. *See Pagan v. Abbott Labs., Inc.*, 287 F.R.D. 139, 148-50 (E.D.N.Y. 2012) ("it is not enough for the Plaintiffs to merely show that the class members . . . purchased recalled Similac; the Plaintiffs need to demonstrate that the recalled Similac that the class members purchased actually contained beetle parts"). Other courts have held the same.[40]

Courts thus consistently refuse to find that a product is defective merely because it was recalled. Remarkably, Plaintiffs' "inventory pool" theory goes farther still. Plaintiffs argue not only that every bottle that came from the 41 recalled lots is defective; they also argue that if any of those bottles were mixed with indisputably non-defective bottles, *all* those bottles then also become defective. This novel theory finds no support in the law; in fact, courts have rejected it. *See Arons*, 2005 WL 975462, at *2, *10 (denying certification where 5,000-tablet bottles of Lipitor that may have included counterfeit product were repackaged into 90-tablet packages, and it was "entirely unclear whether plaintiffs may have been among the unlucky ones who acquired tablets that are actually bogus").[41] And this theory fails on predominance grounds also.

As a threshold issue, Plaintiffs ignore that their "inventory pool" theory makes it more difficult for them to prove predominance, not less. That is because the class indisputably contains members who did not even buy Atorvastatin subject to the recall. Determining which class members actually bought recalled Atorvastatin—and there are more than ten times as many members in the proposed class as there were non-returned recalled bottles—will require

[40] *See, e.g.*, *O'Neil v. Simplicity Inc.*, 553 F. Supp. 2d 1110, 1116 (D. Minn. 2008) (dismissing class action and holding that because a "crib has been recalled, therefore, does not ipso facto mean that the crib has a manifest defect sufficient to permit [the plaintiffs'] claims to proceed"); *Shepherd v. Vintage Pharm. LLC*, 310 F.R.D. 691, 701 (N.D. Ga. 2015) (in a case involving a drug that was recalled due to the fact that a small number of drug blister packs were defectively manufactured, explaining that "to determine the value of what each plaintiff received, she will need to provide some evidence as to whether she received a defective blister pack or not").

[41] *See also Collins v. Safeway Stores, Inc.*, 187 Cal. App. 3d 62, 65, 70-71 (1986) (affirming denial of class certification in a case where 20% of 1.5 million eggs were contaminated and were commingled with other eggs, where "no method existed to distinguish the contaminated [eggs] from the uncontaminated").

individualized inquiry that defeats predominance. *See, e.g.*, *Byrd v. Aaron's, Inc.*, 2017 WL 4326106, at *14 (W.D. Pa. Aug. 4, 2017), *report and recommendation adopted*, 2017 WL 4269715 (W.D. Pa. Sept. 26, 2017) (where plaintiffs' proposed class was overbroad and included members who "would not have been injured by the Defendants' conduct . . . culling these individuals from the pool of plausible claimants will require particularized inquiry").

That courts require plaintiffs to prove they bought a product that was actually defective, not merely recalled, is not surprising. And such actual defect—here, contamination with glass—is what Plaintiffs must prove because their claims require proof of defect, not mere "uncertainty" about a potential defect.[42] This need to prove an actual defect is also squarely in line with testimony from named Plaintiffs, who admitted that if their bottles of Atorvastatin did not contain glass particles, then they are not defective. (*See supra* at 8-9.)

But proving this actual defect on a classwide basis is impossible for Plaintiffs, and the lack of classwide evidence of defect means that there can be no predominance. As courts explain, "[w]here plaintiffs' claims are all based on an alleged common product defect, courts in this District have recognized that *even the basic issue of whether the common defect exists* may defeat predominance and render the class action unmanageable." *Payne v. FujiFilm U.S.A., Inc.*, 2010 WL 2342388, at *1, 3 (D.N.J. May 28, 2010) (putative class action alleging that a digital camera had a defective internal memory battery). This Court similarly found no predominance in a class action where plaintiffs claimed that certain toilet models were defective due to leaks, where "not

[42] *See, e.g.*, *Chin v. Chrysler Corp.*, 182 F.R.D. 448, 460 (D.N.J. 1998) ("unless a product *actually manifests the alleged defect*, no cause of action for breach of express or implied warranty or fraud is actionable"); *Agostino v. Quest Diagnostics, Inc.*, 2011 WL 5410667, at *1 n.2 (D.N.J. Nov. 3, 2011) (unjust enrichment claims require proof of "actual injury"); *Snyder v. Farnam Cos.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (breach of express warranty claim requires "that the product ultimately did not conform to the affirmation, promise or description"); *In re Ford Motor Co. E–350 Van Prods. Liab. Litig. (No. II)*, 2008 WL 4126264, at *19 (D.N.J. Sept. 2, 2008) (breach of warranty of merchantability claim requires, among other things, proof that the product was "not 'merchantable' at the time of sale," as well as "injury and damages to the plaintiff").

all . . . toilets manifest[ed] internal leaking as a result of the alleged defect," and plaintiffs could not "demonstrate that *each* class member's product manifested the actual defect." *Laney v. Am. Standard Cos., Inc.*, 2010 WL 3810637, at *17-18 (D.N.J. Sept. 23, 2010) (Sheridan, J.).

This plainly is not a case where every bottle of Atorvastatin made by Ranbaxy had the same defect. And where individualized inquiry is necessary to find if the product is defective, as would be necessary here, courts routinely find that predominance is not met. *See, e.g.*, *Arons*, 2005 WL 975462, at *20 (finding no predominance in class action over recall of counterfeit Lipitor, because "the evidence does not demonstrate a systemic flaw in the goods" and "the most that may be said is that *some* of the goods sold have the earmarks of something other than authentic Lipitor"; thus, "separate, individual inquiries that test the contents of absent class members' tablets" would be necessary); *Dumas v. Albers Med., Inc.*, 2005 WL 2172030, at *4 (W.D. Mo. Sept. 7, 2005) (in another Lipitor recall case, finding no predominance "[b]ecause of the intensely individualized inquiries that would be required in order to determine what each purchaser actually acquired"); *Pagan*, 287 F.R.D. at 150-51 (in Similac baby formula recall case, finding no predominance due to need for individual inquires to find "who among the class members actually purchased recalled Similac that contained beetle parts"). Court after court has held the same.[43]

Predominance is thus routinely found lacking even where there is evidence that at least *some* of the recalled product was defective, because determining which members actually bought

[43] *See, e.g.*, *Brandner v. Abbott Labs., Inc.*, 2012 WL 195540, at *4 (E.D. La. Jan. 23, 2012) (no predominance because "[w]hether each class member purchased contaminated Similac is subject to individualized, not collective proof"); *In re Digitek Prod. Liab. Litig.*, 2010 WL 2102330, at *1, 17 (S.D.W. Va. May 25, 2010) (in class action involving the drug Digitek, which was recalled after 20 defective tablets were found in a lot of 4.8 million tablets, finding no predominance even though all members of the putative class bought the recalled product, because "[t]here was certainly plenty of recalled Digitek® that was perfectly suitable for human consumption"); *True v. Conagra Foods, Inc.*, 2011 WL 176037 (W.D. Mo. Jan. 4, 2011) (in class action involving recall of pot pies due to possible contamination with salmonella, finding no predominance due to need for individualized inquiry as to whether class members consumed pies that were actually contaminated); *In re Conagra Peanut Butter Prod. Liab. Litig.*, 251 F.R.D. 689 (N.D. Ga. 2008) (denying class certification where most of recalled peanut butter was free of contamination, and many consumers in the proposed class consumed the peanut butter without getting sick).

defective product demands individualized inquiry. Here, where there is no evidence that *any* of the recalled Atorvastatin was defective, the need for individualized inquiry is even greater.

Even if there were any classwide proof of defect here—and there is none—Plaintiffs also ignore the fact that even under New Jersey law, which they contend should apply,[44] each of their causes of action will turn on other individualized questions. For instance, New Jersey requires the buyer to be "aware" of an express warranty for it to become part of "the basis of the bargain." *In re Tropicana Juice Marketing & Sales Practices Litig.*, 2018 WL 497071, at *5 (D.N.J. Jan. 22, 2018); *see also id.* at *7 ("The critical portion of this standard . . . requires that a plaintiff have seen or heard the representation at issue to be considered part of the basis of the bargain.").[45] Determining whether each class member was actually aware of any warranties from Ranbaxy regarding Atorvastatin—a threshold inquiry for this claim—will require individualized inquiry. *See, e.g.*, *Hammer v. Vital Pharm., Inc.*, 2015 WL 12844442, at *9 (D.N.J. Mar. 31, 2015) (finding predominance issues "as to whether the proposed class members ever became aware of the promise"). Here, every named Plaintiff testified they never saw any warranties from Ranbaxy before the recall.[46] These admissions—which foreclose Plaintiffs' express warranty claims—illustrate the importance of these inquiries, yet they simply cannot be done on a classwide basis.

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[44] Mot. at 34-36. For reasons detailed in Section II.C.2, this is incorrect, and the Court would in fact have to apply the laws of the 50 states to this nationwide class.

[45] *See also, e.g.*, *In re: Elk Cross Timbers Decking Mktg.*, 2015 WL 6467730, at *28-29 (D.N.J. Oct. 26, 2015) ("Plaintiffs do not cite relevant law demonstrating that a plaintiff can state a breach of express warranty claim based on representations that they were not even aware of.").

[46] *See* Ex. 16, Fenwick Tr. at 179:22-25 (agreeing that he "had not seen any representations from Ranbaxy before [he] filled [his] prescription"); Ex. 13, Harding Tr. at 24:12-16 (agreeing that "before filling that prescription from Ranbaxy, [he] had never seen any advertising, statements, representations, of any kind from Ranbaxy"); Ex. 14, Safran Tr. at 220:25-221:8 (agreeing he "didn't rely on any warranty from Ranbaxy with respect to this bottle that [he] bought in October 2012"); Ex. 15, Young Tr. at 89:12-20 (agreeing she could not recall "ever seeing any kind of written representation by Ranbaxy prior to the recall in November of 2012"); Ex. 17, Wardrett Tr. at 215:10-13 ("They [Ranbaxy] didn't make no warranty to me."); *id.* at 218:9-12 (agreeing she did not "rely on any representations from Ranbaxy about the generic drugs they sold [her] in this case").

The same is true with regard to Plaintiffs' unjust enrichment and implied warranty of merchantability claims, because they require finding whether each member received the benefit of their bargain. *See, e.g.*, *In re Tropicana*, 2018 WL 497071, at *5 ("A defendant is only unjustly enriched if a plaintiff does not receive the benefit of the bargain for which he or she paid."); *Heindel v. Pfizer*, 381 F. Supp. 2d 364, 379 (D.N.J. 2004) ("breach of implied warranty claims are not intended to address hypothetical economic loss; they are meant to compensate a buyer who has not gotten the benefit of her bargain because the product in question does not meet generally accepted standards or disappoints consumer expectations").

Here, too, it was necessary to individually question named Plaintiffs to determine if they received the benefit of the bargain. Discovery showed they did. For example, all named Plaintiffs admitted they have no reason to believe their Atorvastatin actually contained glass particles. (*Supra* at 7-8.) They agreed they have no reason to think there was anything wrong with their Atorvastatin but for the fact they thought it was recalled. (*Supra* at 8-9.) Nor did they have any reason to doubt that their Atorvastatin was pharmaceutically effective or that it was not pharmaceutically equivalent to brand-name Lipitor. (*Id.*) These inquiries go to the heart of Plaintiffs' claims, but they are impossible to adduce on a classwide basis. Given the individualized inquiries that would be needed for each of Plaintiffs' causes of action, Plaintiffs "cannot credibly show that common questions predominate." *In re Tropicana*, 2018 WL 497071, at *5; *see Grandalski v. Quest Diagnostics, Inc.*, 767 F.3d 175, 185 (3d Cir. 2014) ("the District Court properly found that individual inquiries would be required to determine whether an alleged overbilling constituted unjust enrichment for each class member").

Finally, even if Plaintiffs could prove liability for each of their claims on a classwide basis—which they cannot—calculation of damages for warranty and unjust enrichment claims

under a benefit of the bargain model would be "nearly impossible . . . without individualized inquiries into each claim." *See Martin v. Ford Motor Co.*, 292 F.R.D. 252, 274 (E.D. Pa. 2013); *Spring Motors Distribs., Inc. v. Ford Motor Co.*, 98 N.J. 555, 566 (1985) ("The buyer's measure of damage is the difference between the value of the defective goods and the value they would have had if they had been as warranted."). All five named Plaintiffs paid different amounts for the Atorvastatin they bought;[47] their damages under a benefit of the bargain theory would require an estimate of each of their subjective valuation of the product. (*See* Ex. 1, Strombom Rep. ¶ 51.) But Dr. French agreed that his model does not even try to take into account any "subjective views of what the damages are"; in fact, he admitted that named Plaintiffs' views of their damages are "totally irrelevant to [his] opinions." (Ex. 12, French Tr. at 55:18-56:3, 193:18-194:16.) Instead, Plaintiffs' model assumes that for every member, the value of Atorvastatin they bought was zero, whether they bought pills with glass particles or not. (Ex. 1, Strombom Rep. ¶ 59.) Not only is this assumption contradicted by the testimony of named Plaintiffs in this case (*see id.* ¶ 30 (collecting named Plaintiffs' testimony) and by basic economic theory (*id.* ¶ 59), but it conflicts with settled law as well. *See, e.g.*, *Center City Periodontists, P.C. v. Dentsply Int'l, Inc.*, 321 F.R.D. 193, 212 (E.D. Pa. 2017) ("when calculating damages for breach of warranty, both New Jersey and Pennsylvania credit 'the value of the goods accepted' . . . which includes any value derived from their use"; thus, "it is not true that [product] had 'zero value' at the time of sale").

Plaintiffs' proposed damages model is untethered to the evidence in this case, basic economic theory, and the measure of damages required by law. As the Supreme Court explained

[47] Ex. 1, Strombom Rep. ¶¶ 27-28 & Figure 1 (collecting evidence of the amount of payments by the five named Plaintiffs, and showing that: (1) Fenwick paid $15 for a 90-count bottle of 40mg Atorvastatin; (2) Harding paid $30 for a 90-count bottle of 20mg Atorvastatin; (3) Safran paid $10 for a 90-count bottle of 40mg Atorvastatin; (4) Wardrett paid $1.10 for a 90-count bottle of 20mg Atorvastatin; and (5) Young paid $50.84 for a 30-count bottle of 20mg Atorvastatin, and $20 for two additional 30-count bottles of 20mg Atorvastatin).

in *Comcast Corp. v. Behrend*, "a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to [the] theory [of the case]. If the model does not even attempt to do that, it cannot possibly establish that damages are susceptible of measurement across the entire class for purposes of Rule 23(b)(3)." 569 U.S. 27, 35 (2013). Plaintiffs' flawed damages model is yet another reason why individualized issues predominate.

2. Common Legal Issues Do Not Predominate.

Plaintiffs' argument that New Jersey law should apply to all members, rather than the laws of the fifty states (Mot. at 34-36) is incorrect; in fact, the laws of the 50 states would apply to this nationwide class.[48] This will further complicate the many individual factual issues described above and lead to even further predominance problems—because "if more than a few of the laws of the fifty states differ, the district judge would face an impossible task of instructing a jury on the relevant law," in which case certification is inappropriate. *See Chin*, 182 F.R.D. at 458.[49] Courts thus routinely find that "nationwide state law class actions are unmanageable and cannot be certified." *See Arons*, 2005 WL 975462, at *21 (collecting cases); *Laney*, 2010 WL 3810637, at *22-23 (the "need to apply the laws of each class member's home state," combined with other issues, "create[d] 'insuperable obstacles' to class certification") (Sheridan, J.).

District courts apply the choice-of-law rules of the state in which they sit. *Berg Chilling Sys., Inc. v. Hull Corp.*, 435 F.3d 455, 462 (3d Cir. 2006). New Jersey's choice-of-law analysis is a two-step process. First, the court must determine if an actual conflict exists, by "examining the

[48] Plaintiffs suggest that because Ranbaxy did not raise the choice-of-law issue at the motion to dismiss stage, it cannot do so now. (Mot. at 36.) This is incorrect. The appropriate time for this analysis is at the class certification stage, not the pleadings stage. *E.g.*, *Bang v. BMW of N. Am.*, 2016 WL 7042071, at *5 (D.N.J. Dec. 1, 2016) (deferring resolution of choice-of-law issues to class certification, because that analysis could not be done on facts alleged in the complaint and required discovery); *In re Samsung*, 2009 WL 3584352, at *3 (D.N.J. Oct. 27, 2009) (same).

[49] *See also, e.g.*, *In re Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.*, 276 F.R.D. 336, 341 (W.D. Mo. 2011) ("Several courts have indicated the mere need to engage in a [50-state] analysis—and the exponential increase in the potential grounds for error—demonstrates a class action is inappropriate.") (collecting cases).

substance of the potentially applicable laws to determine whether there is a distinction between them." *See P.V. ex rel. T.V. v. Camp Jaycee*, 962 A.2d 453, 460 (N.J. 2008). Second, if a conflict does exist, the court must determine which state has the "most significant relationship" to the claim, as analyzed under the Restatement (Second) of Conflict of Laws. *Id.* at 455.

Here, this analysis is simple because it has already been done many times before—and courts in this district routinely find that state laws on warranty and unjust enrichment do differ significantly. *See, e.g.*, *Payne*, 2010 WL 2342388, at *9 (explaining that state laws for breach of express and implied warranty "differ greatly" with regard to need to prove reliance, notice of breach, privity of contract, and more);[50] *Vista Healthplan*, 2015 WL 3623005, at *27-30 (finding conflicts in states' unjust enrichment laws); *In re Actiq Sales & Mktg. Practices Litig.*, 307 F.R.D. 150, 164-66 (E.D. Pa. Mar. 23, 2015) (finding conflict in states' unjust enrichment laws and concluding this could lead to differential treatment of claims of the proposed nationwide class); *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 458-59 (D.N.J. 2012) (finding conflicts between New Jersey and California unjust enrichment law).[51]

These conflicts are not hypothetical either; they present themselves even in named Plaintiffs' own claims. For instance, Harding resides in New York, Safran resides in Massachusetts, and Young resides in Texas. (Compl. ¶¶ 8, 9, 12.) Under the laws of their states,

[50] *See also Maloney v. Microsoft*, 2011 WL 5864064, at *5 (D.N.J. Nov. 21, 2011) (same); *In re Digitek*, 2010 WL 2102330, at *8-9 (collecting cases that describe 50-state conflicts for breach of express and implied warranties and unjust enrichment claims).

[51] Plaintiffs point to *In re Mercedes-Benz Tele Aid Contract Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009) to argue that unjust enrichment law does not vary and New Jersey law should apply. But that case is in the minority; in fact, "no subsequent case has followed *Mercedes-Benz*, and many have found that its reasoning went too far." *Avram* v. *Samsung Elecs. Am. Inc.*, 2013 WL 3654090, at *17 (D.N.J. 2013) (collecting cases); *see also Maniscalco v. Brother Int'l (USA) Corp.*, 709 F.3d 202, 210 (3d Cir. 2013) (questioning *Mercedes-Benz*, and noting that "it is far from clear" that New Jersey's "interest in deterring misconduct by corporations headquartered within its borders . . . would be sufficient to outweigh other significant contacts with a plaintiff's home state.").

they would have to show reliance to prevail on their express warranty claim—a highly individualized inquiry—whereas under New Jersey law, they would not.[52]

Given this variability on warranty law, courts routinely find that "the state with the most significant relationship . . . is each class members' home state." *Maloney*, 2011 WL 5864064, at *9; *Payne*, 2010 WL 2342388, at *11; *Arons*, 2005 WL 975462, at *22 (in Lipitor recall case, holding that "the court shall necessarily apply the law of each of the jurisdictions from which potential absent class members acquired their [Lipitor] tablets"). So too for unjust enrichment. *See Vista Healthplan*, 2015 WL 3623005, at *31 ("the state in which the particular purchase was made has the most significant connection to the related claim"); *In re Actiq*, 307 F.R.D. at 167.

Where, as here, the law of more than one state applies, "class action movants must credibly demonstrate, through an extensive analysis of state law variances that class certification does not present insuperable obstacles." *Powers v. Lycoming Engines*, 328 F. App'x 121, 124 (3d Cir. 2009). "This comprehensive analysis is necessary because aggregate class action should not alter the applicable substantive legal rights of the plaintiffs." *Id.*; *see Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 821-23 (1985) (courts "may not take a transaction with little or no relationship to the forum and apply the law of the forum in order to satisfy the procedural requirement that there be a common question of law").

[52] *Compare In re Tropicana*, 2018 WL 497071, at *6 ("New York's incorporation of a reliance element clearly establishes that individualized issues predominate."), *Compaq Computer Corp. v. Lapray*, 135 S.W.3d 657, 676 (Tex. 2004) (under Texas law, "[r]eliance is . . . not only relevant to, but an element of proof of, plaintiffs' claims of breach of express warranty") *and Carter v. Scubapro*, 2011 WL 3107334, at *4 (D. Mass. May 25, 2011) ("Plaintiff has offered no evidence whatsoever of reliance upon . . . any express warranty, thus he has no claim for breach of that warranty under Massachusetts law") *with Arons*, 2005 WL 975462, at *23 (under New Jersey law, "particular reliance need not be shown"). New York law also requires a showing of privity for claims of breach of express and implied warranty, where New Jersey does not. *Compare DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 624 (S.D.N.Y. 2012) (under New York law, "[p]rivity is normally an essential element of a cause of action for express warranty") *and Bristol Village, Inc. v. Louisiana–Pacific Corp.*, 916 F. Supp. 2d 357, 362-63 (W.D.N.Y. 2012) (implied warranty claim under New York law "requires a showing of privity between the manufacturer and the plaintiff") *with Dzielak v. Whirlpool Corp.*, 26 F. Supp. 3d 304, 327 (D.N.J. 2014) (no privity required for claims for breach of implied and express warranties under New Jersey law).

Plaintiffs have made no attempt to meet this burden. They baldly assert that New Jersey law applies—which is incorrect, *see supra* at 30-32. And instead of substantively addressing the very real conflicts in the relevant laws between different states, Plaintiffs simply present this Court with a 50-state chart of the UCC provisions related to express and implied warranty (Pls.' Exs. 17-18) and leave it to the Court to figure it out. That does not come close to meeting Plaintiffs' burden. *See, e.g.*, *Gray v. Bayer Corp.*, 2011 WL 2975768, at *7 (D.N.J. July 21, 2011) (denying certification where the plaintiff "failed to carry his burden" of showing "through an extensive analysis of state law variances, that class certification does not present insuperable obstacles").[53]

Finally, Plaintiffs are incorrect in arguing that New Jersey law should apply simply because Ranbaxy's "headquarters" and "manufacturing facility" were located there. (*See* Mot. at 35.) The fact that a company is domiciled in a state does not establish the most significant relationship. *See, e.g.*, *Feldman v. Mercedes-Benz USA, LLC*, 2012 WL 6596830, at *7-8 (D.N.J. Dec. 18, 2012) (finding that "the law of Plaintiffs' home state" applied to plaintiffs' warranty and unjust enrichment claims, even though defendant was "headquartered in New Jersey," and noting that "this Court follows other cases in this Circuit holding that warranty claims should be governed by the law of each consumer's home state."). Plaintiffs' proposed class includes members who bought Atorvastatin in many states other than New Jersey. In such circumstances, the laws of each of those states will apply. *See, e.g.*, *id.*; *Arons*, 2005 WL 975462, at *22.[54]

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[53] *See also, e.g.*, *Humphrey v. Budget Rent a Car Sys. Inc.*, 2016 WL 3940807, at *11 (E.D. Pa. July 21, 2016) (finding plaintiffs' submission of "three spreadsheets that summarize the elements of her state law claims under each state's law" insufficient to demonstrate that variations in state law do not preclude certification, because "[t]hese charts alone are not sufficient" and "plaintiff has merely shifted the burden to the Court to determine whether state law prevents class certification"); *Cole v. Gen. Motors Corp.*, 484 F.3d 717, 725-26 (5th Cir. 2007) (acknowledging that plaintiffs provided the court with "the statutory text of the warranty and redhibition laws of the fifty-one jurisdictions implicated in this suit," rejecting plaintiffs' reliance "on the textual similarities of each jurisdiction's applicable law," and explaining that "plaintiffs' largely textual presentation of legal authority oversimplified the required analysis and glossed over the glaring substantive legal conflicts among the applicable laws of each jurisdiction").

[54] Plaintiffs also rely on *Elias v. Ungar's Food Prod., Inc.*, 252 F.R.D. 233, 249-51 (D.N.J. 2008). That case is in the minority. *Maloney*, 2011 WL 5864064, at *9 (noting that applying the law of home states is "in accord with great

D. Plaintiffs Have Failed to Prove Superiority Under Rule 23(b)(3).

The second inquiry under Rule 23(b)(3) is whether "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Plaintiffs assert this element is met because there will not be "any difficulty in managing this case." (Mot. at 38.) Plaintiffs are wrong. "[F]requently a finding that individual issues do not predominate is accompanied by a finding that a class action is not superior," because where "a number of 'mini-trials' would be imperative, the costs associated with a class action would be very high; due to the necessary individual litigation of a number of issues, the cost savings [of class litigation] would not be marked." *Sanneman v. Chrysler Corp.*, 191 F.R.D. 441, 454-55 (E.D. Pa. 2000); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 191 (3d Cir. 2001) (holding that court "must address the difficulties likely to be encountered in the management of a class action" when considering the superiority requirement). This would certainly be true here.

The many individual questions of fact that will need to be adjudicated for each class member—not the least of whether they bought Atorvastatin with glass—will "vitiat[e] any potential efficiencies from using the class action mechanism." *Center City Periodontists*, 321 F.R.D. at 213-14. The same goes for the difficulty of managing a class action where, as here, the laws of each class member's home state would apply—which, at the very least, would require an avalanche of different jury instructions. *Vista*, 2015 WL 3623005, at *40; *see also Powers*, 328 Fed. Appx. at 127 ("Attempting to apply the law of a multiplicity of jurisdictions can present problems of manageability for class certification under Rule 23(b) (3)."). Certifying a class here would lead to a "flurry of mini-trials" that will defeat the purpose of the class mechanism. *See Center City Periodontists*, 321 F.R.D. at 213.

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weight of other court decisions in this district" for implied warranty claim). Moreover, *Elias* is also distinguishable because there, the defendants failed to raise specific conflicts in law among the 50 states—as Ranbaxy has done here.

Plaintiffs also argue that individual claims here are not significant enough to justify individual litigation, and thus class action is superior. (Mot. at 39.) But Plaintiffs ignore the equally important consideration of fairness to Defendants, which is "an explicit criterion for a superiority determination." *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 761-762 (3d Cir. 1974). This is particularly true given the weakness of Plaintiffs' claims that discovery revealed. Plaintiffs have not identified a single consumer, including named Plaintiffs, who actually bought Atorvastatin with glass—and the testimony of named Plaintiffs makes clear that absent proof of such defect, they cannot prevail on their claims. Plaintiffs nonetheless seek to certify a nationwide class of over 960,000 persons, even though they cannot prove that even one person was actually harmed. In similar circumstances, courts have found that where the "merits of Plaintiffs' claims are in serious doubt, it would be unfair to put Defendant in a position to settle a non-meritorious action for fear of reputational harm." *Center City Periodontists*, 321 F.R.D. at 213-14; *see also id.* (certification creates "additional settlement leverage which results from the disruption or injury which may occur to a defendant's business relationships regardless of the merits of the claim by the mere sending of the [class certification] notice").

E. Plaintiffs Have Failed to Prove that the Rule 23(a) Requirements Are Met.

To certify a class, Plaintiffs must also prove—again, by preponderance of the evidence—four elements of Rule 23(a): (1) commonality, (2) typicality, (3) adequacy, and (4) numerosity. Plaintiffs have not established any of these elements here, much less all four.

1. Plaintiffs Have Failed to Prove Commonality.

Commonality requires Plaintiffs to show "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). This requires more than raising common questions, "since any competently crafted class complaint literally raises common questions"; instead, Plaintiffs must show questions that are "*capable of classwide resolution*—which means that determination of its

truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). This also "requires the plaintiff to demonstrate that the class members have suffered the same injury," as opposed to simply "suffer[ing] a violation of the same provision of law." *Id.*

Plaintiffs have failed to identify common issues capable of classwide resolution under *Dukes*. Indeed, on very similar facts, the court in *Pagan* found that commonality was not met because "the evidence in this case suggests that most of the members of the class would have not suffered any injury at all because almost all of the recalled Similac did not, in fact, contain any beetle parts." 287 F.R.D. at 148-49. *Pagan* rejected plaintiffs' argument that class members "may have" suffered an injury (just like Plaintiffs here argue that they might have bought contaminated Atorvastatin), finding this insufficient for commonality because "it does not necessarily mean they suffered the same injury under the *Dukes* standard." *Id.* at 148. In fact, the argument for commonality here is even more removed, because in *Pagan*, the plaintiffs were at least able to prove that some portion of the class bought contaminated product; here, there is no such evidence.

Pagan is also consistent with other decisions, which find that commonality in product defect cases is only met when the *same* defect applies to *all* products that class members bought. *See Gonzalez v. Corning*, 317 F.R.D. 443, 494 (W.D. Pa. 2016) (finding that plaintiffs in putative class action arising from purchases of allegedly defective roof shingles failed to prove commonality, absent proof that all shingles were defectively designed); *Cholakyan v. Mercedes-Benz, USA, LLC*, 281 F.R.D. 534, 556 (C.D. Cal. 2012) (no commonality where plaintiff "has not adduced evidence that there is a single source of the alleged injuries suffered by putative class members"). Indeed, courts have concluded that where, as here, "there is simply no general defect

against which to measure defendants' conduct," and it is necessary to examine individual products to identify a defect, "this is the *antithesis* of commonality." *Arons*, 2005 WL 975462, at *18.

Finally, the Third Circuit considers Rule 23(a) commonality to be incorporated into the more stringent Rule 23(b)(3) predominance requirement, and it requires courts to "analyze the two factors together, with particular focus on the predominance requirement." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 (3d Cir. 2004). For all the same reasons Plaintiffs failed to prove predominance, they also fail to prove commonality. (*See supra* Section II.C.)

2. Plaintiffs Have Failed to Prove Typicality and Adequacy.

The typicality requirement "screen[s] out class actions in which the legal or factual position of the representatives is markedly different from that of other members of the class even though common issues of law or fact are present." *Marcus*, 687 F.3d at 598. The "adequacy inquiry seeks to uncover conflicts of interest between named parties and the class they seek to represent." *Schering*, 589 F.3d at 602. And given the "similarity of the typicality and adequacy inquiries," the question of whether the named Plaintiffs' interests align with those of other class members is "relevant under both" those inquiries. *In re Schering Plough Corp ERISA Litig.*, 589 F.3d 585, 601-602 (3d Cir. 2009).

The interests of the three remaining named Plaintiffs are "markedly different" from other class members for at least three reasons. *First*, these Plaintiffs failed to show that they bought Atorvastatin with glass particles, as opposed to other putative class members who may have. Because the latter are the only members who can even claim an Article III injury (*see supra* Sec. I), this presents obvious typicality problems. Indeed, the Court need not look any further than Plaintiffs' "inventory pool" class theory—which Plaintiffs came up with after realizing they have no evidence that any of the named Plaintiffs actually bought contaminated Atorvastatin—to see how just divergent the interests of these named Plaintiffs are from those of other members who in

fact may have bought contaminated Atorvastatin. *See, e.g.*, *Danvers Motor Co.*, 543 F.3d 141, 150 (3d Cir. 2008) (finding adequacy and typicality factors not met because "proposed class members will likely need to pursue different, and possibly conflicting, legal theories to succeed").

Second, named Plaintiffs are "neither typical nor adequate" because they are "subject to . . . unique defense[s] that [are] likely to become a major focus of the litigation." *See Beck v. Maximus, Inc.*, 457 F.3d 291, 301 (3d Cir. 2006). None of named Plaintiffs bought Atorvastatin that actually manifested a defect, which makes them subject to a unique defense. *See, e.g.*, *Pagan*, 287 F.R.D. at 150 (finding typicality and adequacy not met because "the fact that the Plaintiff Pagan's recalled Similac product was found to not contain any beetle parts raises additional unique challenges" to her claim). Moreover, each of the named Plaintiffs admitted they were unaware of any representations from Ranbaxy related to the Atorvastatin they bought. (*See supra* at 27 & n.46); *e.g.*, *Center City Periodontists*, 321 F.R.D. at 207 ("Because awareness of a seller's affirmations is a basic element of a breach of warranty claim in New Jersey and Pennsylvania, Plaintiffs who were not aware of the DFUs' relevant content cannot be typical representatives of a class that was allegedly misled and damaged by Defendant's representations in those same DFUs."). Each named Plaintiff also had a different subjective valuation of their Atorvastatin under the benefit of the bargain analysis. (*See supra* at 28.) Finally, under New York, Massachusetts, and Texas law, Plaintiffs will have to show reliance (which they cannot), and Harding will have to show privity of contract to prevail on his express and implied breach of warranty claims (which he also cannot).[55] These defenses will put named Plaintiffs' focus on their own claims as opposed

[55] Because Harding did not buy his Atorvastatin directly from Ranbaxy but rather bought it from Express Scripts, a pharmacy (Compl. ¶ 9), he cannot show privity. *See, e.g.*, *Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014) (dismissing express warranty claim under New York law because "privity is an essential element" of that claim, absent allegations of personal injuries, but plaintiff did not allege he was in privity with manufacturer).

to those common to the class, which is the antithesis of typicality or adequacy.[56] *See Center City Periodontists*, 321 F.R.D. at 207 (unique defenses make "[p]laintiffs' positions different enough from those of the broader class so as to make it more likely that they will devote time and effort to the defenses at the expense of issues that are common and controlling for the class").

Finally, even under Plaintiffs' unprecedented "uncertainty" liability theory, Plaintiffs have not established that the supposed uncertainty experienced by the named Plaintiffs (if any) is typical of the rest of the class. For instance, named Plaintiffs Harding, Safran, and Young actually knew they bought recalled pills (Harding and Safran from reviewing their bottles, and Young from speaking with her pharmacist). (*See supra* at 5-6.) Ranbaxy advised other consumers to do the same, but Plaintiffs have not established which of the 960,000 members of the proposed class did so. It is very likely that a significant portion of the class did not even learn of the recall and thus experienced no "uncertainty."[57] Moreover, since the majority of the proposed class did not even buy recalled Atorvastatin, the majority of the class experienced no "uncertainty" at all. *See, e.g.*, *Pagan*, 287 F.R.D. at 150 (typicality and adequacy not met where "[t]he claims of the Plaintiffs do not sufficiently relate to those of the proposed class, as the majority of the class members would not have purchased Similac product that contained beetle parts").

3. Plaintiffs Have Failed to Prove Numerosity.

Under Rule 23(a)(1), class actions may be maintained only if "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1). Determining whether a class

[56] Ironically, because Plaintiffs have removed Fenwick—the only New Jersey Plaintiff of the original five—as a class representative, they no longer have a Plaintiff who can assert claims under New Jersey law. *See, e.g.*, *Federman v. Bank of Am., N.A.*, 2014 WL 12774688, at *9-10 (D.N.J. Dec. 16, 2014) (finding that named plaintiff "lack[ed] standing to assert claims under the laws of the states in which he does not reside and in which he suffers no injury").

[57] Ranbaxy documents indicate that Ranbaxy's customer service received roughly 3,000 calls after the announcement of the recall, and its recall coordinator, Inmar, received another 3,667 calls during the month after the recall. (Ex. _24, RANBAXY_FEN0005064.) This number of 7,667 consumers who even inquired about the recall is dwarfed by the 960,000-person class that Plaintiffs are seeking to certify.

is sufficiently numerous "requires examination of the specific facts of each case." *Marcus*, 687 F.3d at 595. "Critically, numerosity—like all Rule 23 requirements—must be proven by a preponderance of the evidence." *Id.*

Plaintiffs argue that numerosity is satisfied here because 960,873 "inventory pool" class members bought Ranbaxy Atorvastatin during the date periods measured by Plaintiffs' expert. (Mot. at 19.) But for reasons explained above, the "inventory pool" class is defective, and the only class that is even arguably valid is a class of purchasers who actually bought contaminated Atorvastatin.[58] Plaintiffs have failed to show that any consumer (including named Plaintiffs) actually bought contaminated Atorvastatin, however, and they present no evidence that such members exist. Numerosity is therefore also not met. *See Pagan*, 287 F.R.D. at 147 (holding, in Similac recall case, that plaintiffs failed to establish numerosity by pointing to the fact that 200,000 class members received a product recall notice, because "the mere receipt of a recall-notification letter does not mean the recipient has any legal claim against Abbott").[59] To hold otherwise would "read the numerosity requirement out of the class action rule," which the Third Circuit has repeatedly warned against. *Marcus*, 687 F.3d at 597.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motion for class certification.

[58] Plaintiffs would face insurmountable obstacles in certifying even such a limited class for other reasons. Just by way of example, Plaintiffs have no way to ascertain such a class (Ex. 12, French Tr. at 241:14-19) (agreeing that his model is not limited "to bottles of Atorvastatin that actually were contaminated with glass particles"), and there would still be no way to determine if members bought contaminated Atorvastatin without individually testing each bottle. *See, e.g.*, Ex. 13, Harding Tr. at 78:18-23 (agreeing that to know "whether [a] particular bottle[] of Atorvastatin contained glass particles, we would have to physically examine it to determine if it did in fact contain glass particles").

[59] *See also Marcus*, 687 F.3d at 597 (finding numerosity not met where plaintiffs put forth evidence identifying car owners with specific brand of tires, but failed to put forth any evidence, beyond named plaintiffs' car, that identified which portion of the class experienced the defect at issue); *Center City Periodontists*, 321 F.R.D. at 209 (holding that while plaintiffs "have adequate estimates for the number of dentists practicing in New Jersey and Pennsylvania," they "merely speculate[d]" as to how many bought the product and used it in a way that showed the defect at issue).

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Respectfully submitted,

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